IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

BRENDA PARRISH, INDIVIDUALLY AND AS ADMINISTRATRIX OF THE ESTATE OF KYLE J. PARRISH Plaintiff vs. MEDTRONIC USA, INC., et al. Defendants	)	CASE NO. 1:19-CV-02995 JUDGE JAMES S. GWIN **PLAINTIFF'S RESPONSE TO DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT FOR FAILURE TO STATE A CLAIM, AND ALTERNATIVE MOTION FOR LEAVE TO AMEND COMPLAINT**

Now comes Plaintiff, by and through undersigned counsel, and hereby submits the following as her Response To Defendants' Motion To Dismiss Plaintiff's First Amended Complaint For Failure To State A Claim And Alternative Motion For Leave To Amend Complaint. Defendants' arguments are premised on a reading of the Amended Complaint which is only supported if the document is not read as a harmonious whole. Plaintiff's Amended Complaint does articulate a plausible set of facts which, if true, constitute a parallel claim, and thus survives preemption. Plaintiff's Amended Complaint identifies a specific federal good manufacturing practices requirement applicable to the specific HVAD at issue, and alleges that the specific HVAD sold to Plaintiff's Decedent was

defective in that it did not conform with this requirement. This is more than sufficient to state a "parallel" claim and press onward with pursuit of the claim on the merits.

Additionally, as it relates to Plaintiff's claims for fraudulent misrepresentation, it is an overstatement to assert that these claims are preempted. Defendant's fraudulent conduct was the promotion of off-label uses which were not subject to the PMA approval and which Defendants knew were far riskier. The FDA declined to permit destination therapy as an acceptable use in announcing the PMA approval of the device. See Exhibit 1, PMA Approval Letter. The Summary of Safety and Effectiveness Data makes clear that the FDA considered, and expressly denied, use of the HVAD for destination therapy pending the results of the Endurance clinical trials. See Exhibit 2, SSED. As use of the HVAD for destination therapy had not received PMA approval from the FDA at the time Mr. Parrish was sold the device, Plaintiff's claims cannot be preempted. Even assuming there is preemption here, Plaintiff's claims are parallel claims in that they raise a valid state law tort claim, and successfully correlate this tort with violation of the PMA by Defendants in promoting off-label uses of the device. As the fraudulent misrepresentations were conducted over a span of several years by multiple agents of Defendants, and Defendants are in sole possession of the identity of those agents, a lenient application of Civil Rule 9(B) is warranted here.

Assuming the Court is not in agreement that the Plaintiff has met the pleading standard articulated in *Iqbal* and *Twombly*, Plaintiff respectfully requests that the Court grant her leave to amend the Complaint pursuant to Fed. R.Civ.P. 15(a)(2). Plaintiffs have given notice to Defendants that they have presented claims for manufacturing defects under the Ohio Products Liability Act, and have pointed to pertinent good

manufacturing practices imposed on Defendants by the FDA which the specific device sold to Plaintiff violates. Defendants have been given fair notice of the nature of the claims against them, and their Motion to Dismiss can be summarized as an assertion Plaintiff has failed to allege pedantic and ultimately formulaic details. If Defendants' concern is that exact sections of the OPLA and IEC-60601-1 are not cited, then they are not warranted a dismissal but a more definite statement. Plaintiff would be severely prejudiced to dismiss the Complaint without affording Plaintiff an opportunity to first amend the Complaint to identify the sections of the OPLA and IEC-60601-1 which are clearly implicated in Plaintiff's Complaint.

For these reasons, Plaintiff respectfully requests that the Court deny Defendant's Motion to Dismiss, as the Complaint has sufficiently plead a parallel claim and thus is not preempted. Should the Court disagree and find Defendants' motion well taken, Plaintiff respectfully requests leave to amend the original state court Complaint to comply with the pleading standards under federal law. Plaintiff's reasoning is more fully stated in the below Brief in Opposition

Respectfully submitted,

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BRIEF IN OPPOSITION

1. SUMMARY OF LAW

I. Preemption and Parallel Claims

"Except as provided in subsection (b) […], no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement-- (1) **which is different from, or in addition to, any requirement applicable under this chapter to the device**, […]." 21 U.S.C. § 360k(a)(1), emph. added. Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements. *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 322, 128 S. Ct. 999, 1007, 169 L.Ed.2d 892, 902 (2008), citing *Medtronic v. Lohr*, 518 U.S., at 495, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996).

In order for a state requirement to be parallel to a federal requirement, and thus not expressly preempted under § 360k(a), the plaintiff must show that the requirements are "genuinely equivalent." *McMullen v. Medtronic, Inc.,* 421 F.3d 482, 489 (7th Cir. 2005), citing *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 453, 125 S. Ct. 1788, 1804, 161 L. Ed. 2d 687 (2005) (emphasis in original). State and federal requirements are not genuinely equivalent if a manufacturer could be held liable under the state law without having violated the federal law. *Id.* at 489. To survive pre-emption, the state-law requirement need not be phrased in the identical language as its corresponding federal requirement. *Bates*, supra at 454.

II. Ohio Products Liability Act – Standard for Pleading Manufacturing Defect

In order for a plaintiff to recover on a products liability claim under Ohio Revised Code § 2307.74, they must establish by a preponderance of the evidence that: "(1) [t]here was, in fact, a defect in the product manufactured and sold by the defendant; (2) such defect existed at the time the product left the hands of the defendant; and (3) the defect was the direct and proximate cause of the plaintiffs' injuries or loss." *Saraney v. TAP Pharm. Prod., Inc.*, No. 104 CV 02026, 2007 WL 148845, at *7 (N.D. Ohio Jan. 16, 2007), citing *State Auto. Mut. Ins. Co. v. Chrysler Corp.,* 36 Ohio St.2d 151, 304 N.E.2d 891, paragraph two of the syllabus (1973); see also *State Farm Fire & Cas. Co. v. Chrysler Corp*., 37 Ohio St.3d 1, 523 N.E.2d 489 (1988).

III. Fraudulent Misrepresentation Claims and Preemption

Courts have held that "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, **when the state claim would not exist if the FDCA did not exist**. *Kubicki on behalf of Kubicki v. Medtronic, Inc.,* 293 F. Supp. 3d 129, 186 (D.D.C. 2018). Where misrepresentation claims are based on independent state law duties that would apply to a seller of a product not subject to any federal regulations who engaged in similar alleged misconduct, they are not impliedly preempted. *Schouest v. Medtronic, Inc.,* 13 F. Supp. 3d 692, 705 (S.D. Tex. 2014), citing *Houston v. Medtronic, Inc.,* 957 F.Supp.2d at 1179 (holding that state fraud-based claims that include off-label promotion allegations are not impliedly preempted under *Buckman* "because they are moored in traditional state common law that exists independently from the FDCA"); see also *Eidson v. Medtronic, Inc.,* 981 F.Supp.2d at 885, 2013 WL 5533081, at *11 (finding that fraud

claims based on off-label promotion escape preemption because such claims "are based on state common law tort duties that exist independently from the FDCA and not solely by virtue of the FDCA").

IV. Civil Rule 9(B) – Less Stringent Application

In cases where the plaintiff is alleging that the fraud occurred over a multi-year period, the plaintiff is not required to allege all facts supporting each and every instance when each defendant engaged in fraud. See *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1051 (9th Cir.2001). When the facts relating to the alleged fraud are peculiarly within the perpetrator's knowledge or control or where fraud occurred over an extended period of time and consists of numerous acts, the specificity requirements of Rule 9(b) are applied less stringently. See, e.g., *United States ex rel. Thompson v. Columbia Healthcare Corp.,* 125 F.3d 899, 903 (5th Cir.1997).

V. Leave to Amend

"In all other cases, a party may amend its pleading only with the opposing party's written consent or the court's leave. **The court should freely give leave when justice so requires**." Fed. R. Civ. P. 15(a)(2), emph. added. Where a complaint fails to plead sufficient facts to state a claim, the plaintiff may seek leave to amend the deficient complaint. It is within the sound discretion of the district court to grant or deny leave to amend, and the district court has discretion to deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party. *Iqbal v. Ashcroft*, 574 F.3d 820, 822 (2d Cir. 2009), on remand from *Ashcroft v. Iqbal*, 556 U.S. 662, 687, 129 S. Ct. 1937, 1954, 173 L. Ed. 2d 868 (2009) ("The Court of Appeals

should decide in the first instance whether to remand to the District Court so that respondent can seek leave to amend his deficient complaint."), citing *McCarthy v. Dun & Bradstreet Corp.,* 482 F.3d 184, 200 (2d Cir.2007).

2. ARGUMENT AND ANALYSIS

I. Plaintiff's Claims Against Medtronic and Heartware For Strict Liability Are Parallel Claims and Thus Not Preempted.

Defendants claim that Plaintiff's claims are preempted by federal law pursuant to the Food, Drug, and Cosmetic Act and the regulations of the Food and Drug Administration. However, a harmonious reading of Plaintiff's Amended Complaint dispels any notion that Plaintiff has failed to raise a parallel claim. Defendants argue this Court should rely on *Riegel* when determining whether common law claims are available to Plaintiffs in products liability suits concerning Class III medical devices which have received Premarket Approval ("PMA") from the FDA. As Defendants correctly state, the *Riegel* court determined:

> "Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> ***1. which is different from, or in addition to, any requirement applicable under this chapter to the device, and***
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter. § 360k(a)."

Riegel v. Medtronic, Inc., 552 U.S. 312, 316, 128 S. Ct. 999, 1003, 169 L.Ed.2d 892, 898 (2008) (emph. added).

However, as Defendants correctly recognized in their Motion to Dismiss, *Riegel* carved out a narrow exception to express preemption for "parallel claims:" state common law claims that are "premised on a violation of FDA regulations" and thus 'parallel,' rather than add to, federal requirements. 552 U.S. at 330 (citation omitted)." (Defendants Reply in Support, 12). In fact, in a similar case to *Riegel*, the Supreme Court of the United States "disclaimed a conclusion that general federal requirements could never pre-empt, or general state duties never be pre-empted," holding in that case "no pre-emption occurred in the case at hand based on a careful comparison between the state and federal duties at issue." *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 322, 128 S. Ct. 999, 1007, 169 L.Ed.2d 892, 902 (2008).

Although the Supreme Court did affirm the lower court's ruling, it held:

> "State requirements are pre-empted under the MDA ***only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. § 360k(a)(1).***
>
> ***Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.*** *Lohr,* 518 U.S., at 495, 116 S. Ct. 2240, 135 L. Ed. 2d 700; see also *id.*, at 513, 116 S. Ct. 2240, 135 L. Ed. 2d 700."

Riegel v. Medtronic, Inc., 552 U.S. 312, 330, 128 S. Ct. 999, 1011, 169 L.Ed.2d 892, 906 (2008).

a. Plaintiff's Amended Complaint plausibly pleads the facts necessary to state a claim of manufacturing defect

In their Motion to Dismiss, Defendants insist that Plaintiffs have failed to raise a parallel claim for a design defect for a multitude of reasons, most of which are based on a reading of Plaintiff's Amended Complaint that does not consider all of the allegations in the Complaint as a unified whole. The intention that the document be read in this way

is expressly stated in Paragraph 1, which states "[t]his Complaint is to be read as one harmonious document, and each paragraph of the Complaint is intended to, and does indeed incorporate the statements contained in every other paragraph of the Complaint as if fully rewritten therein." Amended Complaint, ¶1. In so doing, it is indisputable that Plaintiff has plead all that is required of her to raise a valid parallel claim for a manufacturing defect; she has alleged that the Defendants designed and manufactured the HVAD Device (Amended Complaint ¶¶3, 14, 47, 59); that there are FDA regulations which apply to the HVAD Device (Amended Complaint ¶¶ 52, 53, 54, 56); there was in fact a defect in the HVAD Device (Amended Complaint ¶¶ 57, 59); the defect existed at the time the product left the hands of the Defendants (Amended Complaint ¶¶ 57); and the defect was the direct and proximate cause of the Plaintiffs' injuries or loss (Amended Complaint ¶¶ 59, 60, 61, 62, 63, 64, 65).

b. Plaintiff's claims are not premised on design defect, but plainly state a manufacturing defect was present in the HVAD Device at issue

Contrary to Defendants' assertion that Plaintiff merely "tries to disguise a design defect claim as a manufacturing defect claim," it is clear that when referencing "the HVAD Device" Plaintiff is addressing defects in a very specific HVAD device implanted in her husband on May 5, 2017 (Amended Complaint, ¶2) and that this specific HVAD device was defective in manufacture by differing from identical units and the standards set by the PMA and IEC-60601-1. Amended Complaint, ¶57. There is no assertion in the Amended Complaint that the design of these products generally was defective. Defendants do not contest, and thus concede, that IEC-60601-1 and its subsections are requirement imposed by the FDA on the HVAD Device. Such an argument would be

difficult to raise, as the SSED for the device explicitly lists IEC-60601-1 as a recognized standard of the FDA with which the HVAD is to be in compliance. Exhibit 2, p.5. Defendants do claim, however, that Plaintiff has not specified which FDA-prescribed manufacturing requirement they deviated from. Motion to Dismiss, pp. 15-16. Setting aside Defendants' acknowledgement of IEC-60601-1 as a controlling standard in their own SSED for the HVAD device, it is possible Defendants are claiming Plaintiff has failed to cite the specific subsection of the applicable standard. The standard is voluminous, but from the pages attached here it is clear there are only two sections which concern the "ingress of water" discussed throughout Plaintiff's Amended Complaint. See Exhibit 3, Selected Pages from IEC-60601-1; Amended Complaint ¶¶7, 54, 56. Though the exact citation is not provided, Plaintiff has specified the applicable manufacturing standards which apply to the HVAD Device at issue, and the manner in which the HVAD was defective in a manner failing to meet these standards. Thus Plaintiff has identified the applicable standards with sufficient specificity. See *Kodger v. Zimmer Biomet Holdings, Inc*., No. 1:17-CV-1350, 2017 WL 4348997, at *6 (N.D. Ohio Sept. 29, 2017).

c. Plaintiff's manufacturing defect claims are appropriately plead under the Ohio Product Liability Act

Defendants assert Plaintiff's Amended Complaint fails to properly plead a manufacturing defect cause of action pursuant to the Ohio Product Liability Act by virtue of the fact that the corresponding section of the act is not cited in Plaintiff's Amended Complaint. However, as discussed above, Plaintiff has identified that her claims are premised on manufacturing defect and satisfied the pleading requirements for each of

the factors in succeeding on such a claim, as well as identified that Defendants were in breach of the Ohio Product Liability Act's various statutes which would include O.R.C. 2307.74 concerning manufacturing defect. Amended Complaint, ¶58. Should the Court determine this is insufficient, then the remedy is not a dismissal, but to permit Plaintiff to amend her Complaint to identify the specific statute implicated. See *Kodger*, supra at *6. Many courts have held similarly. See *Boroff v. Alza Corp.,* 685 F. Supp. 2d 704, 709 (N.D. Ohio 2010)("Plaintiff will be permitted to amend her complaint in order to assert the lack of an accurate warning with respect to her OPLA claim."); *White v. DePuy, Inc.,* 129 Ohio App.3d 472, 478 n. 2, 718 N.E.2d 450, 454 n. 2 (requiring the parties to resubmit briefing when neither party had ap-plied the OPLA to product liability claims); *Delahunt,* 241 F.Supp.2d at 844 (dismissing count of complaint without prejudice to be replead pursuant to OPLA).

For the above reasons, Plaintiff has plausibly pleaded a parallel manufacturing defect claim, and Defendants' Motion to Dismiss the Amended Complaint must be denied. Alternatively, the minor defects Defendants allege as to specific citations to law and industry standard can be easily corrected by an amendment to the Complaint, and Plaintiff respectfully requests leave to do so should the Court find Defendants' motion well taken.

II. Plaintiff's Amended Complaint states a valid claim for fraudulent misrepresentation.

a. The sale of the HVAD Device to Plaintiff's Decedent took place prior to receiving PMA for destination therapy, and thus there can be no FDA preemption.

Defendants' assertion that Plaintiff's claims are preempted hinges on the issuance of PMA for the HVAD Device in November 2012. However, the PMA in 2012 was strictly limited to use of the device as a bridge to transplantation of a human heart. The intended use for Mr. Parrish in May of 2017 as a destination therapy was not a use that was approved in the 2012 PMA, and thus the first prong of *Riegel* is not established – without an FDA determination as to the safety of the product for the off-label use, there can be no conflict between the FDA's determination of safety and the State's. As such, Plaintiff's fraudulent misrepresentation claims cannot be preempted, and must be permitted to move forward.

b. Assuming the first prong of *Riegel* is met, preemption does not apply to fraudulent misrepresentation claims.

Plaintiffs do not allege a "fraud on the FDA" claim as Defendants allege; the "fraud" is not on the FDA, but on the Decedent who relied on the company's misrepresentations to his surgeon and the patient community generally. Some courts have found that fraudulent misrepresentations are not expressly or impliedly preempted. The court in *Ramirez* was one such court. In *Ramirez*, the plaintiff's fraud claim was that defendant Medtronic fraudulently concealed information relating to a use of a bone graft product called Infuse that the FDA had not approved. *Ramirez v. Medtronic Inc.,* 961 F. Supp. 2d 977, 997 (D. Ariz. 2013), clarified on denial of reconsideration (Oct. 24, 2013). The court found that by sidestepping the FDA-approved channel, Medtronic opened itself to state law claims based on its off-label promotion. *Id*.;

> "The absence of federal approval of the specific use and the absence of federal regulations that govern how a manufacturer promotes the off-label use of its device means that traditional state-law standards of conduct remain and govern manufacturers' conduct. Section 360k does not apply by its terms to those

> claims. It is true that § 360k might preempt fraud claims (or failure to warn or design defect claims, as discussed below) in other contexts. But in light of the presumption against preemption, **the Court looks at Ramirez's claims in the specific factual context of off-label promotion and not at fraud claims in general. Within the specific scenario that Ramirez has presented, the state law prohibition on fraud will not require Medtronic to do anything different from or in addition to the federal requirements."**

Id., emphasis added. The court found that Ramirez's fraud claim is not impliedly preempted under *Buckman*, because the state law fraud claim exists independent of any federal regulations. *Id.* "Accordingly, Ramirez can bring a claim for fraud based on Medtronic's representations during its off-label promotion efforts." *Id.*

The 9th Circuit Court reached a similar conclusion in *Jones.* The 9th Circuit Court ruled that if the plaintiff had plausibly alleged in her complaint that (a) off-label use of the defendant Medtronic's devices had caused untoward results before the spinal procedures were performed; (b) defendant failed to report such results to the FDA as required; (c) this failure to report caused the FDA not to issue further warnings; and (d) in turn, this failure to warn caused plaintiff's injuries, any such claim would not be preempted. *Jones v. Medtronic, Inc.,* 745 F. App'x 714, 717 (9th Cir. 2018), as amended on denial of re-h'g (Sept. 7, 2018), citing *Stengel v. Medtronic Inc.,* 704 F.3d 1224, 1235 (9th Cir. 2013)("In this case, Medtronic's failure to report was more than a mere misrepresentation to the FDA because it simultaneously misled the device's current and potential users, to whom Medtronic owed an independent duty under state law.")

As Plaintiff has alleged that Defendants' statements were fraudulent misrepresentations of off-label use for the HVAD Device, Plaintiff's claims are like those in *Ramirez* and *Jones* and are thus not preempted.

c. As Defendant is in sole possession of the facts necessary to identify the "who, what, when, where, and how" required by Civ.R. 9(B), a lenient application of the rule is warranted here.

Defendants allege that even if Plaintiff's fraudulent misrepresentation claims are not preempted, that Plaintiff has not met the burden of Civ. R. 9(B) in pleading the fraud with particularity. However, in cases where the plaintiff is alleging that the fraud occurred over a multi-year period, the plaintiff is not required to allege all facts supporting each and every instance when each defendant engaged in fraud. *See United States ex rel. Lee v. SmithKline Beecham, Inc.,* 245 F.3d 1048, 1051 (9th Cir.2001). In addition, when the facts relating to the alleged fraud are peculiarly within the perpetrator's knowledge or control or where fraud occurred over an extended period of time and consists of numerous acts, the specificity requirements of Rule 9(b) are applied less stringently. *U.S. ex rel. King v. Alcon Labs., Inc.*, 232 F.R.D. 568, 570 (N.D. Tex. 2005), citing *United States ex rel. Thompson v. Columbia Healthcare Corp.,* 125 F.3d 899, 903 (5th Cir.1997). See Also *Cooper v. Pickett,* 137 F.3d 616, 627 (9th Cir.1997) (Where complaint asserting claims of improper revenue recognition identified (i) some of the specific customers defrauded, (ii) the type of conduct at issue, (iii) the general time frame in which the conduct occurred, and (iv) why the conduct was fraudulent, it was "not fatal to the complaint that it [did] not describe in detail a single specific transaction ... by customer, amount, and precise method."). Rule 9(b) may also be relaxed to permit discovery in a limited class of corporate fraud cases where the evidence of fraud is within a defendant's exclusive possession. *Lee*, supra at 1052, citing *Wool,* 818 F.2d at 1439; *Deutsch v. Flannery,* 823 F.2d 1361, 1366 (9th Cir.1987). Plaintiff has identified the unknown agents of Defendants, the timeframe in

which their fraudulent statements were made, the targets of those statements, and reliance by Plaintiff and his physicians on those statements. As the statements were over a multi-year period, and made by individuals who Plaintiff could not reasonably identify but who Defendants could easily identify, Plaintiff should be permitted to benefit from a relaxed application of Ci.v R. 9(B) at least until discovery is complete.

III. Assuming Plaintiff Claims Against Medtronic and Heartware Have Not Been Sufficiently Plead, Plaintiff Should Be Granted Leave To Amend Her Complaint.

Fed. Civ.R. 15(a)(2) allows a plaintiff to amend their complaint by seeking leave of the court, and states that leave should be freely given where justice dictates. Fed. Civ.R. 15(a)(2). Justice does so dictate here, as the pleading standard to which Plaintiff complied in drafting her Complaint was not the standard to which Defendants now seek to hold Plaintiff, having successfully removed the case to this Court. Even the Supreme Court in deciding *Iqbal* determined that the plaintiff should be afforded the opportunity to determine whether they may be granted leave to amend their deficient complaint. *Iqbal*, supra at 687. Granting leave is within the discretion of the District Court, and the Court may deny leave for good reason, including futility, bad faith, undue delay, or undue prejudice to the opposing party. *Id.* Defendants' allegations, at their heart, are that Plaintiff merely failed to identify the sections of the IEC-60601-1 and OPLA which apply to her claims. Granting Defendants' Motion to Dismiss on the grounds that Plaintiff did not include formulaic citations to subsections of applicable law and industry regulations would be a windfall for Defendants and a calamity for Plaintiff. There is no futility here, as Plaintiff has shown above that her claims – properly pleaded – are parallel claims and thus not subject to preemption. Nor is there bad faith or undue delay, as Plaintiff

has raised the issue promptly in response to Defendants' allegations that the Amended Complaint was deficient. Further there is no prejudice to Defendants in permitting amendment, but rather it would be highly prejudicial to Plaintiff to dismiss her claims for want of empty verbiage, particularly where she has plead the substance of these sections sufficiently.

For these reasons, Plaintiff respectfully requests leave to amend her Complaint should the Court determine that it is in fact deficient under the Federal Rules.

3. CONCLUSION

Defendants are not entitled to dismissal here as Plaintiff has successfully plead a parallel claim and thus avoided preemption under the Food, Drug, and Cosmetics Act. Should the Court find otherwise, Plaintiff respectfully requests leave to amend her Complaint, as leave should be given freely where justice so requires and a dismissal here for failure to specifically cite to statutory subsections and subsections of industry standards would be highly prejudicial to Plaintiff.

Respectfully submitted,

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/s/ Matthew A. Mooney

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CERTIFICATE OF SERVICE

I hereby certify that on February 19, 2020, a copy of the foregoing Response To Defendants' Motion To Dismiss For Failure To State A Claim, And Alternative Motion For Leave To Amend Complaint was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system. All parties not capable of receiving electronic documents will be served by regular U.S. Mail. Parties may access this filing through the Court's electronic filing system.

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